

REMARKS

Claims 11, 16-18, and 20-46 were pending. Claim 11 has been amended to recite the limitations of claim 30, and also to recite the limitations regarding the enzyme activity, as previously discussed with the Examiner in a telephone interview. Claim 30 has accordingly been canceled without prejudice.

Claims 11, 16-18, 20-29 and 31-46 are now pending.

I. Rejections Under 35 U.S.C. § 103(a) Based on Gebreselassie and Wagenknecht

Claims 11, 16-18, 20-24, 26-42 and 44-46 have been rejected under 35 U.S.C. § 103(a) as obvious based on United States Patent No. 6,379,654 to Gebreselassie et al. ("Gebreselassie") in view of U.S. Patent No. 4,148,872 to Wagenknecht et al. ("Wagenknecht"). Applicants respectfully traverse this rejection on the grounds that a *prima facie* case of obviousness has not been established.

Further to the arguments previously made and already of record in the case, Applicants renew their assertion that there is no motivation to combine the teachings of Gebreselassie and Wagenknecht to arrive at the presently claimed invention. Among other reasons, Gebreselassie teaches that proteolytic enzymes are known to be unstable in a dentifrice environment, and that oral care compositions with enzymes therefore require enzyme stabilizing agents; and Wagenknecht teaches tablet formulations with low levels of water and therefore is not concerned with stabilization of enzymes; thus there is no motivation to combine their teachings.

Even if there were a motivation to combine the two references, there would be no expectation of success as a result. One of ordinary skill in the art would expect, upon viewing the two references in combination, that it would be impossible to incorporate an enzyme into a confectionary composition, because the optimal pH value could not be achieved in the manner taught by Wagenknecht in a chewing gum formulation versus a paste or gel formulation as taught by Gebreselassie. Even if the water amount were then increased to the levels taught by Gebreselassie in order to maximize the enzyme's stability and performance, the resultant composition would have a paste or gel consistency and thus fail as a chewing gum.

Furthermore, as previously argued, the presently claimed invention provides an unexpectedly stable formulation in chewable confectionary form in the presence of a

minimum of water. Finally, the teachings of Gebreselassie and Wagenknecht do not teach each and every element of the pending claims. Neither reference alone, nor the references in combination, teach or suggest the process and stability limitations as recited in amended claim 11. For at least these reasons, Applicants respectfully submit that this rejection has been overcome, and request that it be withdrawn.

II. Rejections Under 35 U.S.C. § 103(a) Based on Gebreselassie, Wagenknecht and Andersen

Claims 25 and 43 have been rejected under 35 U.S.C. § 103(a) as being obvious based on Gebreselassie in view of Wagenknecht and further in view of U.S. Patent No. 5,487,902 to Andersen et al. ("Andersen"). Applicants respectfully traverse.

As discussed above, Applicants maintain their assertion that the addition of Andersen to the teachings of Gebreselassie and Wagenknecht still does not render these claims obvious. Furthermore, Andersen does not cure this defect.

The Office Action states that Andersen "teaches that it is well-known to vary the type and proportions of such ingredients depending on the desired properties of the final chewing gum product." (Office Action, p. 6). However, it must be emphasized that Gebreselassie teaches pastes and gels. Therefore, it is necessary that a skilled artisan, when viewing the teachings of Gebreselassie, would be motivated to develop pastes and gels similar to those taught therein; not to confectionaries such as chewing gums. Even combined with the teachings of Wagenknecht, it would not have been obvious to vary the amount of water in such amounts in order to incorporate an effectively stabilize and optimize enzymes, while still retaining a low water concentration, as recited in present claims 25 and 43. Thus, claims 25 and 43 are not obvious in view of a combination of the teachings of the three references. Furthermore, each of the claim limitations is not taught or suggested by the cited references; specifically, the references do not teach the process and enzyme stability limitations recited in amended claim 11. Accordingly, Applicants respectfully submit that this rejection has been overcome and should be withdrawn.

III. Telephone Interview of December 6, 2006

The *Final Office Action* references the telephone interview between the Examiner and Applicants' representative Rachel J. Lin on December 6, 2006. In that interview, the Examiner indicated that the claims would be allowable if claim 11 was amended to include the process limitations recited in the Specification, page 8, lines 27-31 and the enzyme stability limitations recited in the Specification, page 12, lines 4-5. Applicants have made these suggested amendments herein.

Furthermore, the Examiner indicated that the claims would be allowable if "factual evidence, preferably in the form of a side-by-side comparison, was provided to corroborate Applicants' allegations that the stability outlined . . . was indeed unexpected." (*Final Office Action*, p. 5). Applicants respectfully submit that such evidence of stability has already been provided in the disclosure of the present invention, *e.g.*, in Table III of the Specification, page 11, line 18 to page 12, line 3. Table III shows a comparison of the protease enzyme activity at 4 weeks and 8 weeks between "Table 1" (the designation for a tablet prepared in accordance with the present invention) and "A" (a conventional tablet without enzyme); as well as a comparison between "Table 2" (the designation for a chewing gum prepared in accordance with the present invention) and "B" (a conventional chewing gum without enzyme). It is clear from these results that the compositions of the present invention satisfy the recitation in claim 11 that "wherein the enzyme in said chewable confectionary composition maintains its activity over at least a 4 week period when stored at 23 degrees C."

For at least these reasons, Applicants respectfully submit that the Examiner's requests have been met, and that all rejections have been overcome.

In view of the above amendments and remarks, it is respectfully submitted that the claims are now in condition for allowance, early notice of which is earnestly solicited. Should any outstanding issues remain, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number below.

No fee, other than the fee for the Request for Continued Examination, is believed to be due for the filing of this *Amendment and Response to Final Office Action*. However, the Director is hereby authorized to charge any fees due, and credit any overpayments, to Deposit Account No. 03-2455.

Respectfully submitted,
Du-Thumm *et al.*

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